

REMARKS

In accordance with the above amendments, claims 19-20 and 23 have been amended and claims 1-10, 12, 16-18 and 24-33 have been canceled. New claims 34-51 have been added. Thus, claims 19-23 and 34-51 remain under consideration in this application. No claim has yet been allowed.

Claim Rejections - 35 USC § 112

It is gratefully acknowledged that the rejection under 35 USC § 112, second paragraph, has been withdrawn.

In the claims, new claim 34 parallels former independent claim 10 and is rewritten for clarification. New claims 35-43 depend in some way from claim 34. Claim 49 is similar to former claim 18.

There is believed to be support for all the claims in the material originally submitted.

Care has been taken to introduce no new matter.

It is noted, however, from the Advisory Action dated October 16, 2008 that exception has been taken to the addition of the word "active" to the description of the anti-abuse substance in the claims as possibly introducing new matter. Applicants, however, are convinced that this term is more than adequately supported throughout the original application material. For example, with reference to the original submission document of the present application at page 3, lines 15-19, the anti-abuse substance is described as a "binding agent which immobilizes and

deactivates the abusable substance on contact". That language is also found at page 3, line 29 - page 4, line 3 and page 5, lines 6-10. Thus, the anti-abuse substances in accordance with the present invention treat the abusable substance on contact and for this to occur, the anti-abuse substance necessarily must be in an "active" state, i.e., nothing else is required to activate or trigger the action of the anti-abuse substance. Activated carbon, a preferred anti-abuse substance, is necessarily in an active state.

It is important to note that with the system of the present invention, deactivation of a used transdermal patch is initiated immediately upon proper insertion into a disposal pouch or other contact between abusable substance and anti-abuse material. In this manner and with this design, deactivation initiates under proper treatment after use by a patient and does not wait for an abusive action.

Claim Rejections - 35 USC § 103

In the last Action, the claims under consideration remained rejected under 35 USC § 103(a) as being unpatentable over Marcenyac et al. (U.S. Patent Publication No. 2004/0146547 A1). This rejection is again respectfully traversed for reasons of record and review that follow.

Claims 34-43

Applicants' amended claims clarify what they believe to be clearly patentable subject matter and are believed to also

distinguish over the content of the above cited reference. The present claims 34-43 clearly require an active anti-abuse substance "selected from the group consisting of binding and adsorption agents that prevent later extraction of said abusable substance of interest using a solvent selected from the group consisting of water, ethanol or combinations thereof". (Emphasis added) In claim 40, this is activated carbon.

Marcenyac et al fails to teach or suggest the use of such a binding or adsorption agent which is active and operates on contact to prevent subsequent specific solvent extraction.

It also appears to be the Examiner's position that since there are various inactivating agents available, any substitution among the various inactivating agents is obvious and, in the absence of evidence to the contrary, any suitable specific anti-abuse substances are either anticipated or made obvious by Marcenyac et al.

Applicants must respectfully take issue with this view. This is particularly true in view of the fact that many components that might be put in an anti-abuse composition may not be compatible with each other and may even react with each other so selection is much more than an obvious matter of choice.

Such a difference is particularly important with respect to activated carbon which, the present applicants believe, would be far from an obvious choice for inactivating material in the system disclosed by Marcenyac et al. Activated carbon, those

skilled in the art will recognize, is a non-specific absorbent or adsorbent for organic materials. This means, of course, that it will not discriminate between many types of organic materials which it may contact. Thus, for example, if it is mixed with a dye, it will bind with that dye in the same way it will bind with an abusable drug. Marcenyac et al teaches combining his inactivating agent with a dye (detection material). When this is done, of course, the dye in the material will adsorb on the activated carbon if that were the choice for his inactivating compound. The dye then becomes ineffective as a detection material and the activated carbon ineffective as a binding agent for the drug owing to the possible saturation of binding sites from adsorbing the dye. Although Marcenyac et al allows that the detection material and the inactivating agent may be stored separately (paragraph 0110), they would still be released in a way that interaction between them would immediately inevitably occur.

It should further be noted as in Figure 3 of Marcenyac et al that the inactivating agent is separated from the drug chamber but will be in contact with the skin of a user. If activated carbon is used for the inactivating agent in the embodiment of Figure 3, it will absorb organic materials from the skin, become saturated and thereafter become useless for inactivating the drug after disposal. Contrast this with Figure 2 of the present application, for example, in which the binding agent is in a

reservoir isolated from both the skin and the drug chamber by the removable membrane.

Claims 19-23 and 46-47

In addition, claims 19-23 and 46-47 require a device construction quite unlike any described in the reference. This embodiment requires a patch design and construction that includes a separator membrane between abusable substance and anti-abuse substance which is connected to the skin of a user by an adhering connecting aspect which remains connected to the user and to the separator membrane upon the removal of the patch from the skin of a user and thereby causes the separator membrane to be withdrawn from between the anti-abuse layer and abusable substance causing immediate contact between the two. Nothing resembling this construction is taught or suggested in the cited reference.

This embodiment produces immediate in-activation of the abusable substance upon removal of a patch from a user eliminating the need for any further step. See also Figures 2a and 2b. The anti-abuse technique is fully accomplished simply by the removal of the patch, a necessary act.

Regarding the Examiner's comment, the fact that an overall function may be similar to one shown in the art is irrelevant to patentability when the construction of a device and technique of accomplishing the function are clearly different. The conclusion on page 7 of the Action is clearly not supported by the reference and one cannot simply ignore or gloss over what is clearly a

different and unsuggested construction and associated produced operation as recited in applicants' claims. It is submitted that one would not conceive of applicants' arrangement and technique based on the cited reference. There is no teaching of a separately attached device that withdraws a separation membrane with removal of the delivery patch.

It is the Examiner's view that since the reference teaches the same final result of disposing of the transdermal patch and it is capable of performing a similar function, it meets the claims. Such a view is clearly not proper grounds for rejection of the claims, particularly when it is clear that applicants' device is of a totally different construction and involves a type of automatic anti-abuse aspect that is clearly not present in the Marcenyac device. In addition, it is the construction of the claimed device that dictates the automatic anti-abuse feature and it is susceptible to only one method of proper use. The application of the Marcenyac et al reference to these claims represents an unwarranted overly broad interpretation of both that reference and ignores the importance of the relation of all the elements in the present claims.

The fact that the disposal system of the present invention is initiated immediately upon proper contact between the anti-abuse substance and the abusable substance, also presents an important difference with respect to the efficiency of the drug deactivation process. Thus, the deactivation process is not

necessarily instantaneous and may take time for the drug to diffuse, to contact with the binding agent. Therefore, the faster and earlier the process is initiated, the more efficiently the drug will be bound and misuse prevented.

With the Marcenyac invention, it is directed to a system that includes "a detection and/or inactivating agent that is released when the article or dosage form is misused" (see paragraph 0002 and examples 1-5) emphasis added. It is further noted that the Marcenyac et al system can be defeated if, for example, an abuser finds a way to open the dosage form which does not trigger the "misuse deactivation process". For example, opening the pouch carefully with scissors might accomplish this.

The reference also teaches one to simultaneously incorporate an indelible dye with the inactivating agent for release so as to identify who has tampered with the article. This, of course, would expose persons even properly disposing of the patch to an indelible dye, which is also undesirable.

Cubbage et al (USPN 5,804,215) is cited to show encapsulation of a transdermal patch to prevent access to it. It is believed that this reference fails to remedy the deficiencies of Marcenyac et al with regard to the present claims, which are believed patentably distinct from the combination also.

Thus, in view of the above amendments, taken together with the remarks herein, it is believed that substantial differences have been shown between the present claims and the cited

references which clearly overcome any consideration of obviousness raised by the Examiner. There are significant differences in construction, ingredients and mode of operation between the references and the presently claimed invention which applicants believe has been shown and clearly involve and inventive step.

Accordingly, the Examiner is respectfully requested to reconsider his position, withdraw the present rejections and allow all of the claims.

Should issues remain which, in the opinion of the Examiner, could be addressed by telephone interview, he is invited to contact the undersigned attorney at his convenience to discuss same in an effort to resolve them and expedite prosecution of this application.

Respectfully submitted,

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